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EXAMINER	
SMITH, PRESTON	
ART UNIT	PAPER NUMBER
1794	

NOTIFICATION DATE	DELIVERY MODE
12/11/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

Office Action Summary	Application No.	Applicant(s)	
	10/564,805	SECRETIN, MARIE-CRISTINE	
	Examiner	Art Unit	
	PRESTON SMITH	4152	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *17 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/30/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 9, 14-16 rejected under 35 U.S.C. 103(a) as being unpatentable over Susan E. Carlson, US-Patent 6,306,908 in view of Margaret Ione Halpin-Dohnalek, US-Patent 5,902,578 as evidenced by NPL Bifidobacterial

Referring to claim 1, Carlson teaches an infant formula comprising protein, carbohydrates, and lipids (***column 5, lines 32-35***). Carlson further teaches docosahexaenoic acid and arachidonic acid (***column 5, lines 44-45***). Both docosahexaenoic acid (DHA) and arachidonic acid (ARA) are long chain poly unsaturated acids (LC-PUFA) as can be seen in ***column 3, lines 50-57***). Carlson further teaches the benefits of probiotics (Bifidobacterium) in humans (***column 3, lines 34-38***) however Carlson fails to explicitly teach an infant formula further comprising a probiotic.

Halpin-Dohnalek teaches probiotics (***column 3, lines 44-48***) for use in an infant formula (***column 4, lines 23-25***). It would be obvious to one of ordinary skill in the art at the time that the invention was made to modify the infant formula of Carlson (which reduces the incidence of necrotizing enterocoltis, ***column 3, lines 45-50 of Carlson***) to further comprise the probiotics of Halpin-Dohnalek to further enhance the formula's disease fighting properties (***column 1, lines 45-50*** of Halpin-Dohnalek). (Further, *Necrotizing enterocolitis is a gastrointestinal disease and probiotics such as bifidobacteria are known to reduce the risk of this disease (see NPL Bifidobacterial supplementation reduces the incidence of necrotizing enterocolitis in a neonatal rat model*))

Referring to claim 2, Carlson teaches docosahexaenoic acid (DHA) (***column 5, lines 44-45***).

Referring to claim 3, Carlson teaches docosahexaenoic acid (DHA) (***column 5, lines 44-45***). It is unclear if the DHA content is between 0.2 and 0.5% of the total fatty acids in the lipid source however it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the DHA amounts to produce known effects that would be known to one of ordinary skill in the art for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272,205 USPQ 215 (CCPA 1980).

Referring to claim 4, Carlson teaches docosahexaenoic acid and arachidonic acid (***column 5, lines 44-45***) in a ratio of about 2:1.

Referring to claim 5, Carlson teaches docosahexaenoic acid and arachidonic acid (***column 5, lines 44-45***) in ratio of about 2:1. Even though Carlson does not explicitly teach between 0.8:1 and 1.2:1 it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the DHA or ARA amounts to produce the claimed ratio range in order to produce effects that would be known to one of ordinary skill in the art for the intended application, since it has been held that

discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272,205 USPQ 215 (CCPA 1980).

Referring to claim 6, Halpin-Dohnalek teaches that the probiotic discussed above is a lactobacillus (***column 3, line 45***)

Referring to claim 9, Halpin-Dohnalek teaches that the probiotic discussed above is a lactobacillus and a bifidobacterium together (***column 3, lines 45-46***).

Referring to claim 14, Carlson teaches an infant formula comprising protein, carbohydrates, and lipids (***column 5, lines 32-35***). Carlson further teaches docosahexaenoic acid and arachidonic acid (***column 5, lines 44-45***). Both docosahexaenoic acid (DHA) and arachidonic acid (ARA) are long chain poly unsaturated acids (LC-PUFA) as can be seen in ***column 3, lines 50-57***). Carlson further teaches the benefits of probiotics (Bifidobacterium) in humans (***column 3, lines 34-38***) however Carlson fails to explicitly teach an infant formula further comprising a probiotic.

Halpin-Dohnalek teaches probiotics (***column 3, lines 44-48***) for use in an infant formula (***column 4, lines 23-25***). It would be obvious to one of ordinary skill in the art at the time that the invention was made to modify the infant formula of Carlson (which reduces the incidence of necrotizing enterocoltis, ***column 3, lines 45-50 of Carlson***) to further comprise the probiotics of Halpin-Dohnalek to further enhance the formula's

disease fighting properties (***column 1, lines 45-50*** of Halpin-Dohnalek). (Further, *Necrotizing enterocolitis is a gastrointestinal disease and probiotics such as bifidobacteria are known to reduce the risk of this disease (see NPL Bifidobacterial supplementation reduces the incidence of necrotizing enterocolitis in a neonatal rat model*)) The resulting composition of the references is considered to be capable of strengthening natural immune defenses since it contains all of the components of the claimed composition.

The references do not explicitly teach using the composition to strengthen natural immune defenses of an infant or baby by feeding it to the infant or baby however, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. *In re May,* 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978). Further, while the references do not show a specific recognition of that result, its discovery by appellants is tantamount only to finding a property in the old composition." 363 F.2d at 934, 150 USPQ at 628. Furthermore, reducing necrotizing enterocoltis (***column 3, lines 45-50 of Carlson)*** strengthens the immune system.

Referring to claim 15, since the references contain all of the ingredients of the claimed invention, the resulting composition would provide a complete nutritional need for an infant or baby. Also, Carlson teaches that his formula is nutritionally complete (column 7, line 40) so the formula of the references would be nutritionally complete.

Referring to claim 16, Carlson teaches an infant formula comprising protein, carbohydrates, and lipids (***column 5, lines 32-35***). Carlson further teaches docosahexaenoic acid and arachidonic acid (***column 5, lines 44-45***). Both docosahexaenoic acid (DHA) and arachidonic acid (ARA) are long chain poly unsaturated acids (LC-PUFA) as can be seen in ***column 3, lines 50-57***). Carlson further teaches the benefits of probiotics (Bifidobacterium) in humans (***column 3, lines 34-38***) however Carlson fails to explicitly teach an infant formula further comprising a probiotic.

Halpin-Dohnalek teaches probiotics (***column 3, lines 44-48***) for use in an infant formula (***column 4, lines 23-25***). It would be obvious to one of ordinary skill in the art at the time that the invention was made to modify the infant formula of Carlson (which reduces the incidence of necrotizing enterocoltis, ***column 3, lines 45-50 of Carlson***) to further comprise the probiotics of Halpin-Dohnalek to further enhance the formula's disease fighting properties (***column 1, lines 45-50*** of Halpin-Dohnalek). (Further, *Necrotizing enterocolitis is a gastrointestinal disease and probiotics such as bifidobacteria are known to reduce the risk of this disease (see NPL Bifidobacterial supplementation reduces the incidence of necrotizing enterocolitis in a neonatal rat model*))

Halpin-Dohnalek teaches that her composition is for the prevention of diarrhea (also known as flatulence) (***column 3, lines 31-32).*** Furthermore, the resulting composition from the references would prevent diarrhea or flatulence.

Claim 7 rejected under 35 U.S.C. 103(a) as being unpatentable over Susan E. Carlson, US-Patent 6,306,908 in view of Margaret lone Halpin-Dohnalek, US-Patent 5,902,578 and further in view of Effect of Bifidobacterium longum BB536 yogurt administration on the intestinal environment of healthy adults by T. Ogata.

Referring to claim 7, Carlson teaches the invention as discussed in examiner's address of claim 1 but Carlson fails to teach a Bifidobacterium. Halpin-Dohnalek teaches Bifidobacterium infantis(column 3, line 46) however Halpin-Dohnalek does not explicitly teach Bifidobacterium longum BB 536. Ogata teaches Bifidobacterium longum BB536 (1st paragraph of Ogata). Both species of the Bifodbacteria are known to promote intestinal health (see 1st paragraph of Ogata and see NPL, Bifidobacterium, Learn the Benefits of). Because both species have equivalent functions, a person of ordinary skill in the art at the time of the invention would have recognized the interchangeability of the element shown in the prior art for the corresponding element disclosed in the specification. *Caterpillar Inc. v. Deere & Co.*, 224 F.3d 1374, 56 USPQ2d 1305 (Fed. Cir. 2000); *Al-Site Corp. v. VSI Int' l, Inc.*, 174 F.3d 1308, 1316, 50 USPQ2d 1161, 1165 (Fed. Cir. 1999). The suggestion/motivation for combining the arts would have been to provide a wider selection of Bifidobacteria to be used with this invention for one of ordinary skill in the art at the time of the invention.

Additionally, because both species have equivalent functions, a simple substitution of one known bifidobacterium for another would be obvious because such a substitution would produce predicable results.

Claim 8 rejected under 35 U.S.C. 103(a) as being unpatentable over Susan E. Carlson, US-Patent 6,306,908 in view of Margaret Ione Halpin-Dohnalek, US-Patent 5,902,578 and further in view of Klaske Anna Van Hoey-De-Boer, EP 0904784 A1.

Referring to claim 8, Carlson teaches the invention as discussed in examiner's address of claim 1 but Carlson fails to teach a lactobacillus. Halpin-Dohnalek teaches lactobacillus reuteri (column 3, line 45) however Halpin-Dohnalek does not explicitly teach lactobacillus rhamnosus GG. Van Hoey-De-Boer teaches lactobacillus rhamnosus GG in paragraph 18. Both lactobacillus rhamnosus GG and lactobacillus reuteri are known to promote intestinal health (see paragraphs 17-20 of Van Hoey-De-Boer and column 2, lines 10-30 of Halpin-Dohnalek.) Because both species have equivalent functions, a person of ordinary skill in the art at the time of the invention would have recognized the interchangeability of the element shown in the prior art for the corresponding element disclosed in the specification. *Caterpillar Inc. v. Deere & Co.*, 224 F.3d 1374, 56 USPQ2d 1305 (Fed. Cir. 2000); *Al-Site Corp. v. VSI Int' l, Inc.*, 174 F.3d 1308, 1316, 50 USPQ2d 1161, 1165 (Fed. Cir. 1999). The suggestion/motivation for combining the arts would have been to provide a wider selection of lactobacillus to be used with this invention for one of ordinary skill in the art at the time of the invention.

Additionally, because both species have equivalent functions, a simple substitution of one known lactobacillus for another would be obvious because such a substitution would produce predicable results.

Claim 10 rejected under 35 U.S.C. 103(a) as being unpatentable over Susan E. Carlson, US-Patent 6,306,908 in view of Margaret Ione Halpin-Dohnalek, US-Patent 5,902,578 and further in view of Klaske Anna Van Hoey-De-Boer, EP 0904784 A1 and Effect of Bifidobacterium longum BB536 yogurt administration on the intestinal environment of healthy adults by T. Ogata.

Referring to claim 10, Carlson teaches the invention as discussed in examiner's address of claim 1 but Carlson fails to teach a lactobacillus and bifidobacterium together. Halpin-Dohnalek teaches lactobacillus and bifidobacterium together (***column 3, lines 45-46***) but fails to teach Bifidobacterium longum BB536 and lactobacillus rhamnosus GG.

Halpin-Dohnalek teaches lactobacillus reuteri (column 3, line 45) however Halpin-Dohnalek does not explicitly teach lactobacillus rhamnosus GG. Van Hoey-De-Boer teaches lactobacillus rhamnosus GG in paragraph 18. Both lactobacillus rhamnosus GG and lactobacillus reuteri are known to promote intestinal health (see paragraphs 17-20 of Van Hoey-De-Boer and column 2, lines 10-30 of Halpin-Dohnalek.) Because both species have equivalent functions, a person of ordinary skill in the art at the time of the invention would have recognized the interchangeability of the element shown in the prior art for the corresponding element disclosed in the specification. *Caterpillar Inc. v. Deere & Co.*, 224 F.3d 1374, 56 USPQ2d 1305 (Fed. Cir. 2000); *Al-Site Corp. v. VSI Int' l, Inc.*, 174 F.3d 1308, 1316, 50 USPQ2d 1161, 1165 (Fed. Cir. 1999). The

suggestion/motivation for combining the arts would have been to provide a wider selection of lactobacillus to be used with this invention for one of ordinary skill in the art at the time of the invention.

Additionally, because both species have equivalent functions, a simple substitution of one known lactobacillus for another would be obvious because such a substitution would produce predicable results.

Halpin-Dohnalek teaches Bifidobacterium infantis(column 3, line 46) however Halpin-Dohnalek does not explicitly teach Bifidobacterium longum BB 536. Ogata teaches Bifidobacterium longum BB536 (1st paragraph of Ogata). Both species of the Bifodbacteria are known to promote intestinal health (see 1st paragraph of Ogata and see NPL, Bifidobacterium, Learn the Benefits of). Because both species have equivalent functions, a person of ordinary skill in the art at the time of the invention would have recognized the interchangeability of the element shown in the prior art for the corresponding element disclosed in the specification. *Caterpillar Inc. v. Deere & Co.*, 224 F.3d 1374, 56 USPQ2d 1305 (Fed. Cir. 2000); *Al-Site Corp. v. VSI Int' l, Inc.*, 174 F.3d 1308, 1316, 50 USPQ2d 1161, 1165 (Fed. Cir. 1999). The suggestion/motivation for combining the arts would have been to provide a wider selection of Bifidobacteria to be used with this invention for one of ordinary skill in the art at the time of the invention.

Additionally, because both species have equivalent functions, a simple substitution of one known bifidobacterium for another would be obvious because such a substitution would produce predicable results.

Claims 11-13, 17-21 rejected under 35 U.S.C. 103(a) as being unpatentable over Susan E. Carlson, US-Patent 6,306,908 in view of Margaret Ione Halpin-Dohnalek, US-Patent 5,902,578 and further in view of Zdenek Kratky, US-Patent 6,777,391.

Referring to claim 11, Carlson teaches whey protein concentrate (column 11, line 15) however Carlson does not explicitly teach modified sweet whey proteins with no CGMP or reduced CGMP. Kratky teaches sweet whey proteins that have been modified by the removal of CGMP from the protein (***column 2, lines 36-37***). It would have been obvious to one of ordinary skill in the art at the time of the invention to replace the whey protein concentrate of Kratky with the modified sweet whey protein to reduce the threonine content of the protein (***column 2, lines 36-39***). It is widely known that threonine increases brain glycine which in turn affects neurotransmitter balance in the brain and thus has negative consequences for brain development in the postnatal stages of life (and further, threonine levels are sought to be reduced in infant products). (see NPL).

Referring again to **claim 11**, Kratky teaches from 6 to 50% whey protein (column 2, line 22) and later, Krathy teaches that the whey protein can be sweet whey protein (column 2, line 36). At least 40% falls within this range. Furthermore, to one of ordinary skill in the art at the time the invention was made would have considered the invention

to have been obvious because the compositional proportions taught by Krathy overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the ranges disclosed in the prior art reference, particularly in view of the fact that;

"The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages", In Re Peterson 65 USPQ2d 1379 (CAFC 2003).

Also, In e Geisler 43 USPQ2d 1365 (Fed. Cir. 1997); In re Woodruff, 16 USPQ2d 1934 (CCPA 1976); In re Malagari, 182 USPQ 549, 553 (CCPA 1974) and MPEP 2144.05.

Referring to claim 12, Carlson teaches whey protein concentrate (column 11, line 15) however Carlson does not explicitly teach modified sweet whey proteins with no CGMP or reduced CGMP. Kratky teaches sweet whey proteins that have been modified by the removal of CGMP from the protein (***column 2, lines 36-37***). It would have been obvious to one of ordinary skill in the art at the time of the invention to replace the whey protein concentrate of **Kratky** with the modified sweet whey protein to reduce the threonine content of the protein (***column 2, lines 36-39***). It is widely known that threonine increases brain glycine which in turn affects neurotransmitter balance in the brain and thus has negative consequences for brain development in the postnatal stages of life (and further, threonine levels are sought to be reduced in infant products). (see NPL).

Referring again to **claim 12**, Kratky teaches from 6 to 50% whey protein (column 2, line 22) and later, Krathy teaches that the whey protein can be sweet whey protein (column 2, line 36). At least 60% falls does not fall within this range however it would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the protein percentages, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272,205 USPQ 215 (CCPA 1980).

Referring to claim 13, Kratky teaches proteins present at less than 2 g/100 kcal (***column 9, line 35***).

Referring to claim 17, Carlson teaches an infant formula comprising protein, carbohydrates, and lipids (***column 5, lines 32-35***). Carlson further teaches docosahexaenoic acid and arachidonic acid (***column 5, lines 44-45***). Both docosahexaenoic acid (DHA) and arachidonic acid (ARA) are long chain poly unsaturated acids (LC-PUFA) as can be seen in ***column 3, lines 50-57***). Carlson further teaches the benefits of probiotics (Bifidobacterium) in humans (***column 3, lines 34-38***) however Carlson fails to explicitly teach an infant formula further comprising a probiotic.

Halpin-Dohnalek teaches probiotics (***column 3, lines 44-48***) for use in an infant formula (***column 4, lines 23-25***). It would be obvious to one of ordinary skill in the art

at the time that the invention was made to modify the infant formula of Carlson (which reduces the incidence of necrotizing enterocoltis, ***column 3, lines 45-50 of Carlson***) to further comprise the probiotics of Halpin-Dohnalek to further enhance the formula's disease fighting properties (***column 1, lines 45-50*** of Halpin-Dohnalek). (*Necrotizing enterocolitis is a gastrointestinal disease and probiotics such as bifidobacteria are known to reduce the risk of this disease (see NPL Bifidobacterial supplementation reduces the incidence of necrotizing enterocolitis in a neonatal rat model*)) The resulting composition of the references is considered to be capable of promoting healthy mental development in an infant or a baby since it contains all of the components of the claimed composition.

The references do not explicitly teach using the composition to strengthen natural immune defenses of an infant or baby by feeding it to the infant or baby however, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. *In re May,* 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978). Further, while the references do not show a specific recognition of that result, its discovery by appellants is tantamount only to finding a property in the old composition." 363 F.2d at 934, 150 USPQ at 628.

Carlson teaches whey protein concentrate (column 11, line 15) however Carlson does not explicitly teach modified sweet whey proteins with no CGMP or reduced CGMP. Kratky teaches sweet whey proteins that have been modified by the removal of CGMP from the protein (***column 2, lines 36-37***). It would have been obvious to one of

ordinary skill in the art at the time of the invention to replace the whey protein concentrate of **Kratky** with the modified sweet whey protein to reduce the threonine content of the protein (***column 2, lines 36-39***). It is widely known that threonine increases brain glycine which in turn affects neurotransmitter balance in the brain and thus has negative consequences for brain development in the postnatal stages of life (and further, threonine levels are sought to be reduced in infant products). (see NPL). Referring again to **claim 11**, Kratky teaches from 6 to 50% whey protein (column 2, line 22) and later, Krathy teaches that the whey protein can be sweet whey protein (column 2, line 36). At least 40% falls within this range. Furthermore, to one of ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the compositional proportions taught by Krathy overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the ranges disclosed in the prior art reference, particularly in view of the fact that;

"The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages", In Re Peterson 65 USPQ2d 1379 (CAFC 2003).

Also, In e Geisler 43 USPQ2d 1365 (Fed. Cir. 1997); In re Woodruff, 16 USPQ2d 1934 (CCPA 1976); In re Malagari, 182 USPQ 549, 553 (CCPA 1974) and MPEP 2144.05.

Referring to claim 18, Krathy teaches that a preferred embodiment addresses the nutritional needs and provide for healthy growth of an infant (column 2, line 63-64). This is considered to provide complete nutritional needs of a baby or infant. Also, Carlson teaches that his formula is nutritionally complete (column 7, line 40) so the formula of the references would be nutritionally complete.

Referring to claim 19, the resulting composition of the references is considered to be capable of promoting healthy mental development in a preterm infant since it contains all of the components of the claimed composition.

The references do not explicitly teach using the composition to strengthen natural immune defenses of an infant or baby by feeding it to the preterm infant however, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. *In re May,* 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978). Further, while the references do not show a specific recognition of that result, its discovery by appellants is tantamount only to finding a property in the old composition." 363 F.2d at 934, 150 USPQ at 628.

Referring to claim 20, Krathy teaches proteins present at 1.83 g/100 kcal which falls within the claimed range (***column 9, line 35***).

Referring to claim 21, Kratky teaches from 6 to 50% whey protein (column 2, line 22) and later, Krathy teaches that the whey protein can be sweet whey protein (column 2, line 36). At least 40% falls within this range. Furthermore, to one of ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the compositional proportions taught by Krathy overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the ranges disclosed in the prior art reference, particularly in view of the fact that;

"The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages", In Re Peterson 65 USPQ2d 1379 (CAFC 2003).

Also, In e Geisler 43 USPQ2d 1365 (Fed. Cir. 1997); In re Woodruff, 16 USPQ2d 1934 (CCPA 1976); In re Malagari, 182 USPQ 549, 553 (CCPA 1974) and MPEP 2144.05.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PRESTON SMITH whose telephone number is (571)270-7084. The examiner can normally be reached on 6:30am -5:00pm, Mon-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Del Sole can be reached on (571) 272-1130. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is ava ilable through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

prs

/Joseph S. Del Sole/
Supervisory Patent Examiner, Art Unit 4152